GSAR Case 2006-G522 ST (LT)

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MESSAGE:

RE: GSAR Case 2006-G522; Comments for Submission

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April 2, 2007

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Re: Amendment 2007-01, GSAR Case 2006-G522; GSA Interim Rule Regarding Federal Supply Schedule Contracts-Recovery Purchasing by State and Local Governments Through Federal Supply Schedules

Dear Ms. Duarte:

GlaxoSmith Kline (GSK), a leading research-based pharmaceutical company, appreciates the opportunity to submit comments in response to the General Services Administration's (GSA) interim rule regarding recovery purchasing by state and local governments through Federal Supply Schedule (FSS) contracts ("Interim Rule"). We commend GSA's efforts to facilitate a program under which state and local governments could purchase for emergency and recovery purposes ("Recovery Purchasing Program"). As written, however, the Interim Rule fails to provide adequate guidance regarding the administrative difficulties that will be associated with implementation of the Recovery Purchasing Program. Moreover, because the Interim Rule was drafted broadly to cover all FSS contracts, as currently written it does not address some of the considerations that would affect pharmaceutical companies filling orders under the Recovery Purchasing Program.

A. Opening the FSS to Thousands of Additional Eligible Entities Raises Serious Considerations in Terms of the Ordering Process and Contractors' Delivery Obligations.

GSK is sensitive to the need to have product available in cases of emergency or in response to a disaster or attack. We are concerned, however, that the significant expansion of FSS contracts to include state and local government recovery purchasing could, and most likely would, create a significant increase in demand that potentially could result in supply disruptions for other purchasers.

Specifically, we are concerned that allowing thousands of additional entities to access the FSS contract could impact the ability of manufacturers to meet the needs of primary FSS customers. GSK makes its products available on the pharmaceutical and biologics schedule (FSC Group 65, Part I, Section B). Our core customers are the Department of Veterans Affairs (VA) and the Department of Defense. We also have significant FSS sales to the Indian Health Service and the Centers for Disease Control. It is critical that GSK be able to provide these

agencies with the products that they need on a timely basis. Moreover, because the FSS is a requirements contract, as a practical matter, we are required to meet the ordering needs of our customers, subject to individual order limitations. Additionally, pursuant to the Master Agreement with the VA[1], GSK has agreed to make covered drugs "available" on the FSS contract for procurement by Federal agencies. These obligations necessarily require that GSK maintain a sufficient supply of product to meet the agencies' needs.

Of concern to GSK is the fact that the Interim Rule does not sufficiently address the tension between meeting existing FSS obligations and the additional demand of making product available to thousands of state and local governments for recovery purchasing. The absence of any requirement that eligible purchasers coordinate their ordering activities further increases our concern. GSK respectfully requests that the final rule include clarifying language regarding ordering by state and local entities and the priority of orders received under the Recovery Purchasing Program.

1. Advance Purchasing

The Interim Rule should be revised to allow for more flexibility for FSS contractors regarding advance purchasing. The Interim Rule, acknowledging that a disaster or attack may disrupt state and local government systems, authorizes eligible entities to purchase products or services to facilitate recovery in advance of a disaster or attack.[2] For pharmaceutical products, advance purchasing will consist mostly of product for stockpiles. By their nature, stockpile purchases will be at a higher volume than an entity would normally consume. Therefore, unless the ordering activity provides sufficient notice, a manufacturer may not be able to fulfill a stockpile order. Even where a manufacturer can accept the stockpile order, if it is required to deliver in accordance with its standard FSS delivery clause, there likely will be a risk that it could not meet other product demands. Because stockpile purchases in anticipation of an attack or disaster are not necessarily time sensitive, GSK respectfully suggests that the Interim Rule be revised to allow extension of the delivery time after receipt of an order. This will allow the ability to adjust manufacturing schedules to accommodate the additional orders while still ensuring that product is available for other FSS and commercial purchasers.

2. Emergency Situations

At the other end of the spectrum, the Interim Rule lacks detail as to how the Recovery Purchasing Program will function in the wake of a widespread attack or disaster. In that case, thousands of Federal, state, and local agencies will be ordering product at the same time. Where the event was unforeseen or where there was little advance warning, it is highly likely that there will not be sufficient supply on hand to fulfill all state and local government orders as well as Federal orders. The Interim Rule should be revised to address the priority of orders in an emergency situation. For example, are manufacturers expected to fill Federal orders first and

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[1] The Master Agreement implements requirements of the Veterans Health Care Act of 1992, 38 USC § 8126.
[2] 72 FR at 4651.

then fill state and local orders on a first come first served basis, or should there be some apportionment of product to meet the immediate needs of as many agencies as possible? Moreover, the logistical difficulties of reviewing thousands of orders, verifying ordering activity eligibility, and negotiating new contracts would be virtually unworkable in a true emergency where time is of the essence. Therefore, there needs to be more guidance regarding how to proceed in the aftermath of a widespread disaster or attack so that manufacturers and ordering activities can plan accordingly.

B. The Interim Rule Should Provide a Clear Post-Event Time Limit and Other Safeguards to Protect Against Abuse of the Recovery Purchasing Program.

While the Interim Rule establishes a triggering event for recovery purchasing – a major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or a terrorist, nuclear, biological, chemical or radiological attack[3] – it provides no clear end date for recovery purchasing. The lack of an end date, coupled with the authority for advance purchasing – i.e., to purchase products in anticipation of a potential disaster or attack, could be interpreted to permit an open-ended ability on the part of state and local entities to access FSS contracts. As discussed above, the uncertainty inherent in having thousands of additional entities eligible to purchase off of individual contracts under the Recovery Purchasing Program places a significant burden on manufacturers from a product availability and order processing standpoint. Moreover, because there are no clear temporal limits on ordering under the Recovery Purchasing Program, the Recovery Purchasing Program is susceptible to abuse. Put another way, as currently written, the Interim Rule does not provide adequate safeguards to prevent ordering activities from procuring product at any time, purportedly for disaster recovery, but then improperly using the products for non-recovery purposes. We therefore suggest that the final rule implement stricter time limitations that allow for recovery purchasing relating to a particular disaster or attack only during a specified period after a triggering event and require ordering entities to certify that product is not being misused and to allow and cooperate with periodic audits to verify the same.

C. The Interim Rule Should Be Revised to Clarify that Contractors Will Have the Ability to Establish Additional Contract Terms in Agreements with State and Local Purchasers Under the Recovery Purchasing Program.

As currently written, the Interim Rule contemplates that when a state or local entity seeks to purchase under the Recovery Purchasing Program, a separate contract between the purchaser and manufacturer will be established. The new contract will incorporate most FSS contract clauses as well as additional terms and conditions proposed by the ordering activity to implement state statutes and regulations:

> When the Contractor accepts an order from such an entity, a separate contract is formed which incorporates by reference all the terms and conditions of the Schedule contract except the Disputes

[3] 72 FR at 4653; GSAR 538.7102.

> clause, the patent indemnity clause, and the portion of the Commercial Item Contract Terms and Conditions that specifies 'Compliance with laws unique to Government contracts' (which applies only to contracts with entities of the Executive branch of the U.S. Government).
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> * * *
>
> Ordering activities may include terms and conditions required by statute, ordinance, regulation, order or as otherwise allowed by State and local government entities as a part of a statement of work (SOW) or statement of objective (SOO) to the extent that these terms and conditions do not conflict with the terms and conditions of the Schedule contract.[4]

We strongly suggest that the Interim Rule be revised to allow ***contractors*** to add terms to the new contracts. This is necessary for two reasons. First, given the nature of pharmaceutical products, it is imperative that manufacturers have the ability to craft the contract to ensure that the purchasing agency be licensed to store and dispense pharmaceuticals and to require proper use and disposal of the products. Because FSS contracts are drafted broadly to cover all commercial items, they do not include some of the clauses that are considered standard in a contract for the supply of pharmaceuticals. There should be a mechanism for including such industry-standard provisions when they are not suggested by the ordering activity. Second, allowing each contractor a meaningful opportunity to define the products it is willing to supply and to establish the terms and conditions under which such products would be supplied is the only way to ensure that the Recovery Purchasing Program continues to be voluntary, as expressly provided in the authorizing legislation. Without the ability to truly negotiate contract terms, it could create a situation where orders are unnecessarily rejected. Allowing flexibility would permit GSK to work with the ordering entity to reach an agreement that is appropriate.

D. The Five-Day Rejection Period Provides Insufficient Time to Negotiate a New Contract.

The Interim Rule creates an FSS contract clause that permits the contractor to reject orders as follows:

> The Contractor is encouraged, but not obligated, to accept orders from such entities. The Contractor may, within 5 days of receipt of the order, decline to accept any order, for any reason. The Contractor shall fulfill orders placed by such entities, which are not declined within the 5-day period.[5]

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[4] 72 FR at 4654-55; GSAR 552.238-80(a)(1), (3) (Feb 2007).
[5] 72 FR at 4655 (Feb. 1, 2007); GSAR 552.238-80(a)(5).

The five-day rejection period provided for in the Interim Rule resembles the period under the FSS contract for rejecting an order of a non-Executive agency.[6]

While five days may be enough time to reject an order from an agency under an established contract, it is insufficient in the context of recovery purchasing by state and local governments. Five days is simply not enough time to review and negotiate the terms and conditions of a new contract. This is especially true where a manufacturer may be required to negotiate with the thousands of entities potentially eligible to purchase under the Recovery Purchasing Program and where a manufacturer receives orders from many entities at the same time. Ultimately, a strict five-day rejection period could result in unnecessary rejections of orders where, if more time had been allotted for order review, they could have been accepted and filled.

In addition, assuming acceptance of orders if not rejected within a specified period undercuts the voluntary nature of the Program. As discussed above, the legislation that authorized the creation of the Program expressly provided that participation would be voluntary. To meet this statutory requirement, GSK suggests that no order be deemed accepted until some affirmative action is taken by the applicable FSS contractor to accept such order.

E. The Final Rule Should Provide For Direct Notification Upon Placement of an Order.

Given the realities of the pharmaceutical sales process – including purchasing off of the FSS contract – we suggest that the Interim Rule be revised to require notification of the FSS contractor (either directly by the ordering entity or by a designated third party) upon placement of each order. GSK sells the vast majority of its products to commercial and government customers mostly through third parties – wholesalers and distributors. This is the case for sales under the FSS to purchasers that are not eligible to purchase through the government prime vendors. Accordingly, even where a customer is authorized to access the FSS contract directly, often it will simply contact the distributor and reference the FSS contract number. The distributor will then extend the FSS contract price to the customer.

This wholesaler transaction occurs without GSK's involvement or knowledge. GSK is first notified of the sale when it processes a chargeback from the wholesaler weeks or months after the transaction. The chargeback compensates the distributor for the difference between the price it paid for the product and the contract price (a price negotiated between the manufacturer and the end-customer) on which the distributor based its price to the customer.

The Interim Rule, as currently written, could result in state and local entities following the same process – i.e., contacting their wholesalers, notifying them that they are eligible for the FSS price under the Recovery Purchasing Program, and the wholesaler processing the orders without giving the contractor an opportunity to reject. Accordingly, GSK strongly suggests that the final rule require notification of the FSS contractor (either directly by the ordering entity or

[6] I-FSS-103, Scope of Contract – Worldwide (July 2002) (Variation).

by a designated third party) at the time of ordering and some affirmative action by the contractor to accept the order before any order is filled. Moreover, in the event that an ordering activity purchases product through the wholesaler *without* notifying the contractor or prior to the contractor's affirmative acceptance, the contractor should have the right to reject the chargeback submitted by the wholesaler (in essence, be permitted to retroactively refuse to extend FSS pricing to that ordering activity). Note, however, that once the manufacturer has been contacted, the parties would not be precluded from agreeing that the order will be shipped and/or invoiced through a wholesaler.

As is evident, if state and local governments were to purchase through distributors and wholesalers without prior notification of, and acceptance by, FSS contractors, the Recovery Purchasing Program would cease being voluntary in nature. Importantly, the statute that authorized the Program, Section 833 of the John Warner National Defense Authorization Act for Fiscal Year 2007,[7] explicitly states that "participation by a firm that sells to the Federal Government through the supply schedule shall be voluntary with respect to a sale to the State or local government through such supply schedule."[8] The only way that the Program can be truly voluntary, however, is if the eligible purchasers are clearly required to contact the manufacturer directly when placing an order, so that the contractor has a genuine opportunity to evaluate and reject orders. GSK's suggested revision gives the contractor the visibility it needs to make an informed decision while maintaining the flexibility of the parties to negotiate an arrangement that is appropriate in the circumstances.

F. The Final Rule Should Establish a Concrete Way for Manufacturers To Identify Eligible Entities.

As currently drafted, the Interim Rule allows for participation in the Program of thousands of state and local entities. We suggest that the final rule provide for more detailed information regarding the state and local entities that are considered eligible to purchase under the Program. As currently written, the Interim Rule defines only general categories of eligible entities, (e.g., "....states of the United States, counties, municipalities, cities, towns.....school districts, colleges and other institutions of higher education....").[9] At a minimum, we suggest that there be a centralized electronic list of all eligible state and local ordering activities and their respective authorized ordering officials. This type of system is especially important with respect to the pharmaceutical and biologics schedule because there are clear restrictions on where and to

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[7] Pub. L. 109-364 § 833(a); 40 USC § 502(d). The statute provides for the Secretary of the Department of Homeland Security (DHS) to make a determination regarding which schedules will be available for recovery purchasing. DHS has determined that state and local governments may access all supplies and services offered on FSS contracts for recovery purchasing. *See* Frequently Asked Questions about Disaster Recovery Purchasing, http://www.gsa.gov/Portal/gsa/ep/contentView.do?faq=yes&pageTypeId=8199&contentId=22410&contentType=GSA_OVERVIEW.

[8] 40 USC § 502(d)(3); P.L. 109-364 § 833.

[9] 72 FR at 4650, 4654.

whom product can be shipped. Manufacturers are permitted to ship product only to licensed pharmacies that can properly store and dispose of the product.[10]

One option for implementing the Recovery Purchasing Program is to establish a Prime Vendor program similar to that employed by Health Resources and Services Agency (HRSA) for its Public Health Service (PHS) 340B Program.[11] A Prime Vendor program would allow for pre-registration of eligible entities, verification that the entities meet threshold requirements (e.g., state licensing and storage capability) and commitment by the entities to comply with certain terms and conditions (e.g., that they will not divert product, that they will maintain separate inventories, that they will permit and cooperate with periodic audits). Engaging a Prime Vendor to coordinate and manage entity eligibility would ease the significant administrative burden that would otherwise fall on contractors and would enable pharmaceutical manufacturers to more effectively participate in the Program.

G. GSA Should Clarify That Recovery Purchasing Sales are "Federal."

Inclusion of language in the Interim Rule stating that sales to state and local entities under the Recovery Purchasing Program[12] are considered Federal sales is critical because treatment of these sales as non-Federal could result in their inclusion in the calculation of pricing under various Federal pricing programs in which GSK participates. These include the Medicaid Average Manufacturer Price (AMP) and Best Price,[13] the Average Sales Price (ASP) and the Non-Federal Average Manufacturer Price (Non-FAMP)[14], which is used to calculate the Federal Ceiling Price that caps the pricing charged to VA, DoD, PHS, and the Coast Guard on VA FSS contracts. The Medicaid statute specifically exempts from Best Price, "any prices charged under the Federal Supply Schedule of the General Services Administration."[15] Likewise, Federal sales are not included in the Medicaid AMP and ASP calculations or the calculation of the Non-FAMP weighted average. If FSS-priced sales were included in these various programs, they would influence Federal pricing and reimbursement rates – a situation clearly not intended under the statute that created the Program.

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[10] The receiving facility would also need a way to maintain a separate inventory to prevent disaster recovery product from being used for non-disaster purposes.
[11] The 340B Prime Vendor Program is currently managed by HPPI.
[12] Moreover, sales to state and local government under this Program at pricing below the FSS price should also be considered Federal sales.
[13] 42 USC § 1396r-8(k)(1); 42 USC § 1396r-8(c)(1)(C)(i).
[14] 38 USC § 8126(h)(5).
[15] 42 USC § 1396r-8(c)(1)(C)(i)(II).

GSK appreciates the opportunity to comment on the important issues raised by the Interim Rule, and we look forward to working with the government to ensure that state and local agencies continue to have access to critical pharmaceutical agents. We hope that the government will give due consideration to our comments and will incorporate our suggestions into its final rule. Thank you for your attention to this important matter.

Respectfully submitted,

David Brown

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